Office Action. Specifically, claims 7, 8 and 10 were indicated as being rejected, but the body of the rejection applies to claims 7, 8 and 19. It is assumed that the rejection applies only to claims 7, 8 and 19, and not to claim 10. Accordingly, the rejection will be discussed with respect to claims 7, 8 and 19. Without acquiescing in the rejection, claim 19 has been canceled without prejudice and claims 7 and 8 have been amended for clarity. Accordingly, the rejection is traversed, and reconsideration and withdrawal thereof are respectfully requested.

The rejection of claims 1-4, 7, 9 and 11-18 under 35 U.S.C. §103(a) over John (U.S. Patent No. 6,067,467) in view of Webb et al. "Closed-loop control of depth of anaesthesia" (hereinafter Webb) is respectfully traversed. Without acquiescing in the rejection, claims 1 and 7 have been amended for clarity. Accordingly, the rejection will be discussed with respect to the amended and pending claims.

John is directed to an electroencephalograph (EEG) method to monitor patients during and after medical operations. According to John, an anesthesiologist administers sufficient anesthetics to cause the patient to attain a desired plane of anesthesia. The patient's brain waves, both ongoing and evoked by stimuli are amplified, digitized and recorded. The pre-operative set of brain wave data is compared to a set of the patient's brain wave data obtained during the operation in order to determine if additional, or less, anesthesia is required, paying particular attention to the relative power in the theta band, as an indication of brain blood flow, and prolongations of the latency periods under brain stem stimuli, as an indication of the patient's ability to feel pain. A set of neurometric

features are extracted, converted into a normalized statistical score, a discriminant score is thereby developed and the discriminant score is converted into a patient state index using probability functions.

John does not teach or suggest the calculation of an index relating to the depth of anesthesia based upon the coarseness of the measured signal as a single measured value, as specifically set forth in the claims. Instead, John presents a complex method based on the statistical analysis and weighting of a number of EEG parameters. According to John, each parameter is assigned a score that is calculated from the differences of pre-operative and intra-operative measurements that are weighted and summed to give two numerical measures for state while the patient is (1) awake; and (2) unconscious. The weighting used for these two states differ and are based on "experience and experimentation" (see, e.g., Col. 10, lines 21-22). From the resulting measures, the probability of the patient being awake or unconscious is calculated (see, e.g., Col. 10, lines 30-40).

Webb is directed to improving the use of neural networks in analyzing and evaluating AEP signals for use in an anesthetic control system. Webb does not disclose, teach or suggest calculation of an index relating to the depth of anesthesia based upon the coarseness of the measured signal, as specifically set forth in the claims.

In complete contrast to the combination of John and Webb, the claimed invention specifically recites a method for calculating an index relating to the depth of anesthesia based upon the coarseness of a single measured signal (e.g., AEP). There is no

recognition, teaching or suggestion in John of simply measuring this individual parameter, i.e., coarseness of AEP, and determining therefrom an index indicative of anesthetic depth. Instead, and in stark contrast, John presents a complex statistical analysis and weighting of a wide variety of different EEG parameters to arrive at his depth of anesthesia determination. The claimed method is completely distinct from the complex multi-variable approach of John in that the claimed invention analyzes the morphology of one signal, i.e., the coarseness of AEP, to calculate an index indicative of anesthetic depth.

Simply stated, there is no teaching or suggestion in either John or Webb of calculating an index relating to the depth of anesthesia based on the coarseness of the AEP signal. Even if, *arguendo*, the combination of John and Webb were proper, the combination would result in a system in which EEG and AEP are used in a complex statistical analysis to determine a probability of a patient being awake. Moreover, combination even when made fails to disclose or suggest using the coarseness of the AEP signal as set forth in the claims. Accordingly, the combination of John and Webb fails to render the claimed invention obvious. Therefore, reconsideration and withdrawal of the rejection are respectfully requested.

The rejection of claims 8 and 10 under 35 U.S.C. §103(a) over John '467 in view of Webb and further in view of Cosgrove, Jr. et al. (U.S. Patent No. 4,280,494, hereinafter "Cosgrove") is respectfully traversed. Without acquiescing in the rejection,

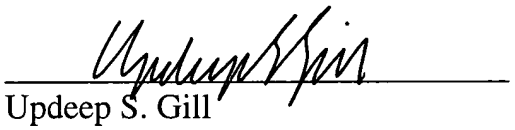
claim 8 has been amended to correct its dependency. Accordingly, the rejection will be discussed with respect to the claims as amended.

It is respectfully submitted that Cosgrove fails to overcome the fundamental deficiencies noted above with respect to John and Webb. Therefore, even if, arguendo, the combination of Cosgrove, John and Webb were proper, the combination nevertheless fails to render the claimed invention obvious. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

In view of the foregoing, it is respectfully submitted that the entire application is in condition for allowance. Favorable reconsideration of the application and prompt allowance of the claims are earnestly solicited.

Should the Examiner deem that further issues require resolution prior to allowance, the Examiner is invited to contact the undersigned attorney of record at the telephone number set forth below.

Respectfully submitted,
NIXON & VANDERHYE PC



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MARKED-UP VERSION OF AMENDED CLAIMS

1. (*Amended*) A method of calculating an index indicative of anaesthetic depth, the method comprising:

subjecting a patient to a repetitive audio stimulus[,];

monitoring auditory evoked potentials (AEP) produced by the patient[, and];

providing a signal corresponding to the coarseness of the monitored AEP signal, the coarseness of the signal being a measure increasing with amplitude and frequency of variations in the signal AEP; and

using said signal as said index indicative of anaesthetic depth.

7. (*Amended*) A method as claimed in claim [6] 4, wherein for a moving time averaged sweep this measure is a function of the sum of the square roots of the difference between every two adjacent sample points in the time averaged sweep.

8. (*Amended*) A method of maintaining closed-loop control of an anaesthesia depth, the method comprising supplying a dosage of anaesthetic to a patient, calculating an anaesthetic depth index according to [the above first aspect of the present invention] claim 1, and using the value of the anaesthetic depth index to regulate the

anaesthetic supply to maintain the anaesthesia depth index at or near a predetermined level.